MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM

REGULATORY GUIDE NO. 3.0
Revision 1.0
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GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR NON-MEDICAL USE OF RADIOACTIVE MATERIAL

Massachusetts Department of Public Health
Radiation Control Program, 5th Floor
174 Portland Street
Boston, MA 02114

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I. INTRODUCTION

A. Purpose of Instructions

This guidance document describes the type of information needed by the Agency to evaluate an application for a specific license for the possession and non-medical use of radioactive material. This type of license is provided for under the Massachusetts Regulations for the Control of Radiation (105 CMR 120.000 et. seq.), hereafter called the Regulations.

This document is intended solely for guidance in the preparation of the license application and should not be considered a substitute for the applicant's careful safety evaluation of the proposed use of radioactive material. The applicant must ensure that the application correctly and adequately describes his/her radiation safety measures and procedures.

B. Purpose of Appendices to this Guide

The regulations require licensees to develop and implement written policies and procedures which ensure compliance with the regulations. The attached appendices provide sample radiation safety procedures which the licensee may choose to use in their radiation safety program. Applicants should carefully read the applicable regulations and sample procedures and then decide if the sample procedures are appropriate for their specific radiation safety needs. In the application, applicants may certify that they will follow a sample procedure or develop and submit an equivalent procedure for Agency review. If a sample procedure is followed, applicants must ensure that references to that procedure are clear and specific (e.g., references should include guide number, revision number, revision date and appendix identification).

C. Applicable Regulations

The requirements for Specific Licenses are codified in the Regulations under the general heading of Specific Licenses (105 CMR 120.124 through 120.135). Other areas of the Regulations that are applicable to this type of license are:

105 CMR 120.001 - "General Provisions";
105 CMR 120.100 - "Licensing of Radioactive Material";
105 CMR 120.200 - "Standards for Protection Against Radiation";
105 CMR 120.750, "Notices, Instructions, and Reports to Workers: Inspections" describes training information;
105 CMR 120.770, "Packaging and Transportation of Radioactive Material"
105 CMR 120.890, "Low-level radioactive waste minimization regulations general provisions".

The Agency may amend these regulations periodically to remain compatible with current standards. The licensee will be notified of these changes as they occur and should incorporate them into their program, if applicable.

D. Retention of Records

The licensee must maintain certain records for specified periods of time for compliance purposes. These intervals have been established in order for the inspection staff and other authorized entities to have access to these documents as required by the regulations. Appendix A contains the retention requirements for these documents.

E. Radiation Protection Program

As specified in 105 CMR 120.210, the licensee must develop, document, and implement a radiation protection program. Specifically, this program should include provisions for ensuring compliance with the requirements of Part D of the regulations, the license, the license conditions with all active amendments and for establishing an ALARA program and for performing reviews of the program at 12 month intervals. In developing a radiation protection program, the licensee should design the program based on the size of the facility, potential hazards associated with radiation exposure, the potential for intake of radioactive material, and the physical characteristics of the radionuclides.

Active control over the radiation protection program should be exercised by management personnel in positions of authority. In addition, management should be aware that the assignment of duties to individuals (e.g., the Radiation Safety Officer) does not relieve management of the responsibilities to review and control the licensed activities.

F. As Low As is Reasonably Achievable (ALARA)

Persons engaged in activities authorized by radioactive material licenses issued by the Agency must to the extent practicable, make every reasonable effort to maintain the release of radioactive material and the total effective dose equivalent (TEDE), ALARA, for both workers and members of the public. License applicants must give consideration to the ALARA philosophy when designing facilities, procuring equipment and for developing procedures for work with radioactive material. The ALARA concept is a key element in establishing any radiation protection program as described above. The definition of ALARA may be found in 105 CMR 120.005.

G. Systéme International (SI) Units

The Agency is making an effort to implement the SI system of units. If applicants wish to utilize SI units in their

application, please feel free to do so. However, this conversion is by no means mandatory at this time. The Agency will continue to recognize SI and English units. Appendix B of this guide has been included to assist applicants in the use of SI units.

II. FILING AN APPLICATION

An application for a specific license for non-medical use of radioactive material can be made by completing Agency form MRCP 120.100-4 (Attachment A) as follows:

1. Complete Items 1 through 4 and 13 on the form itself. For Items 5 through 12, submit the required information on supplementary pages.

2. Identify and key each separate sheet or document submitted with the application to the item's number of the application to which it refers.

3. All typed pages, sketches, and, if possible, drawings should be on 8-1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8-1/2 x 11 inches.

4. Complete all items in the application in sufficient detail so that the Agency can determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life and property.

5. Please note that license applications are available for review by the public. Do not submit proprietary information unless necessary. If proprietary information is submitted without proper documentation that confidentiality must be maintained, there may be disclosure of the proprietary information to the public or time-consuming delays in processing your application.

6. Do not submit personal information about your individual employees unless it is pertinent to the application. Training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. A person specifically listed as an authorized user on an existing radioactive material license may submit a copy of that license (or reference an Agency Radioactive Material License Number) as evidence of training and experience. Submit home addresses and home telephone numbers only if they are part of an emergency response plan. Do not submit birthdates, Social Security numbers, and radiation dose information unless specifically requested by the Agency.

7. The application should be completed in triplicate. The original and one copy of the application, along with duplicate copies of supporting documents, should be sent to:

   Massachusetts Department of Public Health
   Radiation Control Program
   174 Portland Street, 5th Floor
   Boston, MA 02114

8. Retain one copy of the entire application for yourself. The license is issued based on the statements and representations in your application and any supplements to it, as well as the requirements in the regulations.

III. INFORMATION TO BE SUBMITTED

Since the space on the application form is not sufficient to contain all the required information, additional sheets should be appended.

Each separate sheet or document submitted with the application should be identified by a heading indicating the appropriate application item number and its purpose.

Item 1 - LICENSE INFORMATION

For a new license, check subitem A. For an amendment to an existing license, check subitem B. For a renewal of an existing license, check subitem C.

Item 2 - APPLICANT'S NAME AND MAILING ADDRESS

If you are filing as an individual, you should be designated as the applicant only if you are acting in a private capacity and the use of the radioactive material is not connected with your employment with a corporation or other legal entity. Otherwise, the applicant should be the corporation or other legal entity applying for the license.

The address specified here should be the applicant's mailing address for correspondence. This may or may not be the same as the address at which the material will be used as specified in Item 3.

Item 3 - LOCATIONS OF USE

Specify each location of use. List the street address, city, and state or other descriptive address (such as 5 miles from the intersection of Route 32 on Highway 10, Anytown, State) to allow

us to locate your facilities. A post office box address is not acceptable.

If you plan to use radioactive material at more than one location, you must give the specific address of each location. You also must describe the intended use and the facilities and equipment at each location. Use Items 5 through 11 of the application to describe uses at multiple locations.

Item 4 - PERSON TO BE CONTACTED ABOUT APPLICATION

Provide the name and telephone number of the individual who is most familiar with your proposed radioactive materials program and can answer questions about the application. This individual, usually the RSO or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the Agency if the individual assigned to this function changes. Notification of a contact change is for information only and would not be considered an application for a license amendment.

Item 5 - RADIOACTIVE MATERIAL

Describe the radioactive material by isotope, chemical and/or physical form, and activity in becquerels (or millicuries or microcuries). A separate possession limit for each nuclide should be specified. Possession limits requested should cover the total anticipated inventory, including stored materials and waste, and should be commensurate with the applicant's needs and facilities for safe handling.

If the use of sealed or plated sources is contemplated, the isotope, manufacturer, and model number of each sealed or plated source should be specified. If a source will be used in a gas chromatograph, gauge, or other device, the manufacturer and model number of the device should be specified.

Item 6 - PURPOSE

The use to be made of the radioactive materials should be clearly described. Sufficient detail should be given to allow a determination of the potential for exposure to radiation and radioactive materials of both those working with the materials and the public.

Item 7 - INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAMS--THEIR TRAINING AND EXPERIENCE

A. All licensees must have a radiation protection officer, designated by and responsible to management, for implementing the radiation safety program. State his/her name and title. Describe his/her experience in using radiation and radioactive materials, and his/her training in radiation protection. A statement describing his/her responsibilities and authority for carrying out the radiation safety program should be provided.

B. Specify the names of the person(s) who will directly supervise the use of radioactive material or who will use radioactive material without supervision.

Item 8 - TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

All individuals whose jobs may require them to access any portion of a restricted area must receive instruction as specified in 105 CMR 120.753. Submit a description of the training that will be provided to all personnel who work with, or in the vicinity of, radioactive materials. This training description should include the form of training (e.g., formal course work, lectures), a list of topics covered in the training, the means used to evaluate the training (e.g., exam), the frequency of training, the duration of training, the name and qualifications of the individual providing the training, and a sample of the training record to be maintained (or a description of such records content and the subject matter). The training program should be of sufficient scope to ensure that all personnel, including technical, clerical, maintenance, housekeeping, and security personnel, receive proper instruction in items such as those outlined in Appendix G. These topics may vary depending on staff members job-related duties.

Regarding the frequency of personnel training, such training must be provided to personnel before assuming duties in, or performing duties requiring access to, any portion of a restricted area, at intervals not to exceed 12 months as refresher training, and whenever there is a significant change in duties, potential radiation hazards, regulations, or the terms of the license.

Item 9 - Facilities and Equipment

9.1 Physical Facilities.

Submit annotated diagrams, and written descriptions if necessary, of all areas in which radioactive material will be used or stored (e.g., *in vitro* laboratories, hot laboratories, radioactive waste

storage rooms, etc.). A sample diagram can be found in Appendix F. Submitted diagrams should:

1. Specify the diagram scale and identify areas of interest within each room, such as radioactive material preparation areas, waste storage areas, package receipt areas, hot sinks, etc.

2. Indicate the direction of north.

3. Clearly mark or identify all areas adjacent to radioactive material use/storage rooms or areas (e.g., offices, hallways, restrooms, etc.).

4. Specify the building, floor, room number, and principal use of each room or area.

5. Note the presence of shielding in rooms or areas on the diagram [and indicate thickness and composition].

6. Specify any available radiation safety equipment for rooms or areas such as fume hoods, L-blocks, remote handling equipment, storage containers, etc.

7. Clearly identify all area(s) assigned for receipt, storage (including waste), preparation, and measurement of radioactive material.

8. Specify all pertinent airflow rates, filtration equipment, and monitoring instrumentation available in rooms or areas in which radioactive material could become airborne.

9. Indicate all lockable doors, storage containers, and security measures for all use/storage locations for radioactive material.

9.2 - Instrumentation

Specify by manufacturer and model number, all radiation measuring/monitoring instruments and detectors to be used at the facility. This list shall include, but is not limited to, fixed area monitors, instruments for analysis of wipe tests, and instruments for performing area surveys. The applicant must submit calculations to show that the instrumentation used to analyze wipe test samples is sufficiently sensitive to detect [220 dpm/100 cm^2, beta/gamma]. Appendix D contains information regarding minimum detectable activity calculations.

Exhibit B is a form that may be used to describe the applicant's instrumentation. If this form is not used, then submit equivalent information.

9.3 - Instrument Calibration and Operability Checks

The licensee must ensure that the survey instruments used to demonstrate compliance with 105 CMR 120.225 are calibrated prior to first use, at intervals not to exceed 12 months thereafter, and also following repair. Specify if survey instruments will be calibrated by a service company specifically licensed to perform survey instrument calibrations as a customer service or by the applicant using specified procedures.

If survey instruments are to be calibrated by the applicant, then the applicant must submit the information requested in Appendix E. If a consultant or other licensed firm will perform the calibration of the survey instruments, then the applicant should maintain a copy of the radioactive material license which authorizes that entity to perform survey instrument calibrations as a customer service. If other instrumentation such as area monitors are to be calibrated as well, these should be addressed in this section.
In addition, the Agency requires the licensee to check instrument operability by using a dedicated check source, and maintain records of these checks. These instrument operability checks are required to be performed on each day that the instrument is used; however, a record of these checks is required only after repair, battery change, or instrument calibration, and at intervals not to exceed three months. If any check source reading varies greater than 20% from the reading measured immediately after calibration, the licensee shall require that the instrument be repaired or recalibrated before use for compliance surveys.

For these instrument operability checks, the term "dedicated check source" means that:

A. The sealed source used must contain a radionuclide with a relatively long half-life (e.g., greater than five years).

B. The sealed source used to check an instrument's operability must remain the same throughout the time period between survey instrument calibrations or repairs (e.g., the source must be the same model and serial number used previously for that particular model and serial number survey instrument).

   Note that this does not prohibit the licensee from using the same sealed source as the dedicated check source for more than one survey instrument. It only requires that the sealed source used initially by the licensee upon return of that survey instrument from repair or full calibration must remain the same until that survey instrument is later calibrated.

Item 10 - RADIATION SAFETY PROGRAM

10.1 Personnel Monitoring. Personnel monitoring is required if a person is likely to receive in a calendar year 5mSv (500 millirems) total effective dose equivalent (or 10% of this value in the case of a minor). Personnel monitoring is also required if a person enters a high radiation area (greater than 100 millirems per hour). If personnel monitoring equipment will be used, the name of the organization furnishing film badge or thermoluminescent dosimeter (TLD) service and the frequency for changing badges, dosimeters, etc., should be specified. If direct reading dosimeters (pocket ionization chambers) will be used, the useful range of the device, in milliroentgens, the frequency of reading and the procedures for maintaining and calibrating the devices should be specified.

If personnel monitoring will not be used, the applicant should submit calculations or documentation from radiation surveys that demonstrate that it is unlikely that any individual will receive a dose equal to or greater than that indicated in the preceding paragraph.

Appendix P contains a sample procedure for use and calibration of direct reading dosimeters. If direct reading dosimeters are used, either indicate that the procedure contained in Appendix P will be followed or submit an alternate procedure for Agency review.

10.1(b) Bioassays

Bioassays are required when individuals are likely to receive an intake in excess of 10% of the annual limit on intake. Bioassays are normally performed when individuals work with millicurie quantities of unsealed hydrogen-3, iodine-125, or iodine-131, depending on the chemical and physical form, the procedures followed and the equipment used to make it possible for radioactive materials to be ingested, inhaled, or absorbed into the body. The applicant should indicate the need for bioassays has been thoroughly considered and should describe his proposed bioassay program, if applicable. U.S. NRC Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program" [or Agency-specific guide] may be of assistance in preparing these descriptions.

Appendix N contains a sample procedure to be followed when performing radioiodine bioassays. If radioiodine is to be used, verify that procedures contained in Appendix N will be followed or submit an alternate procedure for Agency review.

10.A.-Health Physics Program Written radiation safety procedures to be followed by users should be provided as part of the application.

10.A.1.- Procedure for Ordering and Receiving Radioactive Material

Submit a description of procedures for ordering and receiving radioactive material, including receipt during off-duty hours, and for notification of responsible persons upon receipt of radioactive material. This procedure should be adequate to meet the requirements of 105 120.235 and 120.246, to ensure that possession limits are not exceeded, to ensure that radioactive material is secured at all times against unauthorized removal, to ensure that radiation levels in unrestricted areas do not exceed the limits specified in 105 120.221, and to ensure that all receipts are properly documented.

Security personnel or any other individuals who receive packages of radioactive material during off-duty hours should be issued written procedures which detail receipt, examination, and security for packages. Procedures should include notification procedures to be followed for packages found or suspected to be leaking and indicate the immediate steps to be taken to prevent the spread of contamination.

Appendix H contains a sample procedure and instructions for ordering and receiving radioactive material packages.

10.A.2 - Procedure for Safely Opening Radioactive Material Packages

Submit procedures for examining incoming packages for leakage, contamination, or damage, and for safely opening packages in accordance with 105 CMR 120.246. Package monitoring should be performed as soon as practicable after receipt. This procedure may vary depending on the type and quantity of radioactive material received, but it should include instructions for surveying packages, wearing gloves while opening packages, checking packing material for contamination after opening, and verifying the contents of packages of radioactive material, not only against the packing slip, but also against the amount, type, and form of material ordered. Even though 105 CMR 120.246 exempts certain packages from monitoring, it is necessary that procedures be established for safely opening all radioactive material packages.

Appendix I contains a sample procedure for safely opening packages of radioactive material. Either indicate that the procedures contained in Appendix I will be followed or submit an alternate procedure for Agency review.

10.A.3 - General Rules for the Safe Use of Radioactive Material

Submit the general safety instructions to be followed by all personnel while working with radioactive materials. The instructions should:

A. Explain what safety apparel to wear and what equipment to use (e.g., wearing laboratory coats, eye protection and disposable gloves, and using transport carts and shielding).

B. Indicate what personnel monitoring devices to use when handling radioactive material.

C. Specify limitations and conditions for handling liquid or unsealed sources of radioactive material and the safety equipment to use when working with them.

D. Specify the shielding or remote handling equipment to be used when handling beta and/or gamma emitting materials.

E. Include guidance concerning security of radioactive material.

F. Provide instructions for movement of radioactive material between rooms, in halls, or in corridors.

G. Provide guidance on waste disposal requirements.

H. Describe contamination control procedures including prohibitions against smoking, eating, drinking, or the application of cosmetics, and prohibiting the storage of personal items (food, drink, cosmetics, etc.) in areas where radioactive material is used or stored. In addition, include instructions to individuals for performing radiation surveys of their hands, clothing, etc. after working with radioactive material.

Appendix J contains a sample set of general rules for safe radioactive material use, which may be appropriate for smaller or limited programs. Either indicate that the procedure contained in Appendix J will be followed or submit an alternate procedure for Agency review.

10.A.4 - Emergency Procedure

Submit a copy of emergency procedures. A copy of these procedures should be posted in all areas where radioactive material is used/stored and should:

A. Describe immediate action to be taken after an incident in order to prevent contamination of personnel and work areas (e.g., turning off the ventilation, area evacuation, and

spill containment). Actions to be taken for handling injured personnel who may be contaminated should also be addressed, if applicable.

B. List the names and telephone numbers of the responsible persons (e.g., RSO) to be notified in case of an emergency. The Agency's 24-hour number should be included in this section (617/727-9710).

C. Instruct personnel on appropriate methods for re-entering and decontaminating contaminated areas.

D. Describe what action is to be taken in the event of fire, theft, or loss involving radioactive material. This response must include the notification of this Agency in accordance with 105 CMR 120.281 and 120.282.

Appendix K contains a sample emergency procedure. Either indicate that the procedure in Appendix K will be followed or submit an alternate procedure for Agency review.

10.A.5 - Area Survey Procedure

The licensee must establish and agree to implement written procedures for performing periodic radiation surveys and contamination monitoring. The procedures must describe the routine survey program, including the areas to be surveyed, frequency of the surveys, action levels initiating decontamination procedures, and provisions for maintaining records of surveys.

If the application is to cover multiple users and areas of use, the individual user should perform surveys of his own work areas in addition to those performed by the radiation safety staff.

Appendix L contains sample area survey procedures for use of unsealed radionuclides. Either indicate that the area survey procedures described in Appendix L of this guide have been adopted or submit an alternate procedure for performing routine radiation surveys and contamination monitoring for Agency review.

10.A.6 - Testing Sealed Sources for Leakage and/or Contamination

Testing of sealed sources for leakage and/or contamination shall be performed only by persons who are specifically licensed by either the Agency, another Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission (NRC) to perform such services. In establishing a program for testing for leakage and/or contamination in accordance with 105 120.315 and 120.520, two alternatives are available from which to choose:

A. The services of a licensed consultant or commercial organization may be used to obtain test samples, evaluate the samples, and report the results back to the applicant. In addition, a commercially available test kit may be used to obtain a test sample for subsequent analysis by a licensed service company. When using a licensed service, please note the licensee should maintain a copy of that company's license which authorizes them to perform tests for leakage and/or contamination as a customer service.

B. The applicant may request authorization to perform tests for leakage and/or contamination, including sampling and analysis. If this option is chosen, then submit the information outlined in Appendix M for Agency evaluation.

10.A.7 - Procedure for Use of Radioactive Gases/Volatile Material

The use of radioactive gases and volatile materials requires attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive material in restricted and unrestricted areas, including effluents released to the atmosphere. Each applicant who wishes to use these forms of material must submit unrestricted area concentration calculations to the Agency in support of that request as well as document personnel exposures as a result of restricted area releases in accordance with 105 CMR 120.212 and 120.213. If ventilation systems are used in conjunction with radioactive gases/volatile material, procedures for use and maintenance of these systems should be included in the application.

Appendix O contains sample calculations. The applicant should refer to the sample calculations in Appendix O to compile information in support of a request to use radioactive gases or volatile material.

10.A.8 - Procedure for the Use of Radioactive Material in Animals

The licensee should submit specific procedures to be followed if radio-nuclides will be used in animals. These should include: (1) a description of the dedicated animal housing facilities, (2) a copy of instructions provided to animal caretakers for handling animals, animal wastes, and carcasses, (3) instructions for cleaning and decontaminating animal cages, (4) procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material, and (5) procedures for disposal of animal carcasses and associated waste in compliance with 105 CMR 120.255. If radioactive material will not be used in animals, please so indicate.

Item 11 - WASTE MANAGEMENT

11.1 Waste Disposal

Submit your procedures for waste disposal. Provide a complete description of specific methods used for waste disposal of radioactive material. A licensee may dispose of waste by:

1. Transfer to a persons properly licensed to receive such waste; i.e., commercial radioactive waste disposal firms.

2. Release into air in conformance with 105 CMR 120.222 the Regulations.

3. Incineration only if specifically authorized by the Agency in accordance with 105 CMR 120.254 of the Regulations.

4. Release into a sanitary sewer in conformance with 105 CMR 120.253 of the Regulations. (You should describe your methods for controlling the sewage disposal of radioactive wastes in order to ensure that disposals do not exceed the limits specified in 105 CMR 120.222).

5. The disposal of radioactive material by storage means that the material is allowed to decay to concentrations which do not exceed those specified in 105 CMR 120.195: Appendix A, (Exempt Concentrations), before discarding the material.

All solid wastes potentially contaminated with radioactive material should be monitored with a suitable instrument to ensure that no detectable radioactivity remains before disposal by normal methods. Any shielding materials should be removed before monitoring.

Massachusetts Law prohibits the disposal of radioactive material by burial within the Commonwealth of Massachusetts.

11.2 Waste Minimization

105 CMR 120.890 requires that all radioactive material users, as well as all generators of radioactive waste, prepare statements indicating the measures they have taken to minimize any waste that may result from their operations. Those applicants whose operation result in 100 cubic feet or more of waste per annum, and such waste requires disposal, must develop and institute waste minimization programs predicated on detailed plans. Provide an appropriate document that applies to your operation.

Item 12 - ORGANIZATIONAL STRUCTURE

Provide an organizational chart both for the institution, showing Administration, Radiation Safety Committee and Radiation Safety Officer, and for the corporate structure and ownership. Identify the state of incorporation, and provide the names of principal stockholders, if applicable. List parent companies, names, addresses, and titles of principals. List percentages of partners, shares, state of incorporation, and other organizational details that may be important during financial or legal circumstances.

Item 13 - CERTIFICATION

Identify the title of the office held by the individual who signed the application.

BEFORE SUBMITTING IT, REVIEW YOUR APPLICATION TO BE SURE YOU HAVE RESPONDED TO EACH ITEM AND TO BE SURE THAT EACH PAGE THAT YOU HAVE ATTACHED HAS AN ATTACHMENT NUMBER AND IS DATED.

IV. AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations and procedures contained in the license application and supportive documents. The license MUST BE AMENDED if the licensee plans to make any changes in facilities, equipment (including monitoring and measuring instruments), procedures, personnel or radioactive material used.

Applications for license amendments may be filed either on the application form or in letter form. The application should identify the license by number and should clearly describe the exact nature of the changes, additions and/or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page and paragraph.

V. RENEWAL OF A LICENSE

A radioactive materials license expires five (5) years from the last day of the month in which it was issued. An application for renewal of a license should be filed at least thirty (30) days PRIOR TO the expiration date. This will ensure that the license does not expire until final action on the application has been taken by the Agency as provided for in 105 CMR 120.133.

Renewal applications should be filed on the forms provided by the Agency for this purpose. The application should contain complete and up-to-date information about the applicant's current program. In order to facilitate the review process, the application for renewal should be submitted without reference to previously

submitted documents and information. If such references cannot be avoided, they should be clear and specific and should identify the pertinent information by date, page and paragraph.

VI. LICENSE TERMINATIONS

A licensee may request termination of a radioactive material license at any time. To terminate a license, the licensee must meet the requirements of 105 CMR 120.132 which include:

1. Transfer or disposal of all licensed radioactive material in the licensee's possession in accordance with 105 CMR 120.256;

2. Notification of Agency of termination of licensed activity;

3. Performance of radiation surveys or the equivalent in accordance with 105 CMR 120.132(D)(1)(e).

   Submit the completed Termination Form MRCP 120.100-3 and a copy of any applicable radiation surveys to the Agency at least 30 days before the expiration date of the license or upon termination of all licensed activities. The Agency reserves the right to perform confirmatory surveys of licensed facilities prior to termination.

APPENDIX A

RETENTION OF DOCUMENTS

I. PERMANENT JOB SITES

Document	Retention Interval
Regulations	Until termination of license
License, all active amendments and supporting documents(including the application)	Until termination of license
Annual ALARA Reviews	5 years
Receipt, Transfer and Disposal	Until disposal is authorized by the Agency
Survey Instrument Calibration	5 Years
Leak Tests	5 Years
Inventories	5 Years
Utilization Logs	Until disposal is authorized by the Agency
High Radiation Area Control Devices or Alarm Systems	Until disposal is authorized by the Agency
Training and Testing Records	Until disposal is authorized by the Agency or 3 years after termination of employment
Personnel Monitoring Records and Pocket Dosimeter Readings	Until disposal is authorized by the Agency
Pocket Dosimeter Calibrations	5 years
Alarm Ratemeter Function Checks	5 years
Alarm Ratemeter Calibrations	5 years

APPENDIX A - RETENTION OF RECORDS

I. PERMANENT JOB SITES (continued)

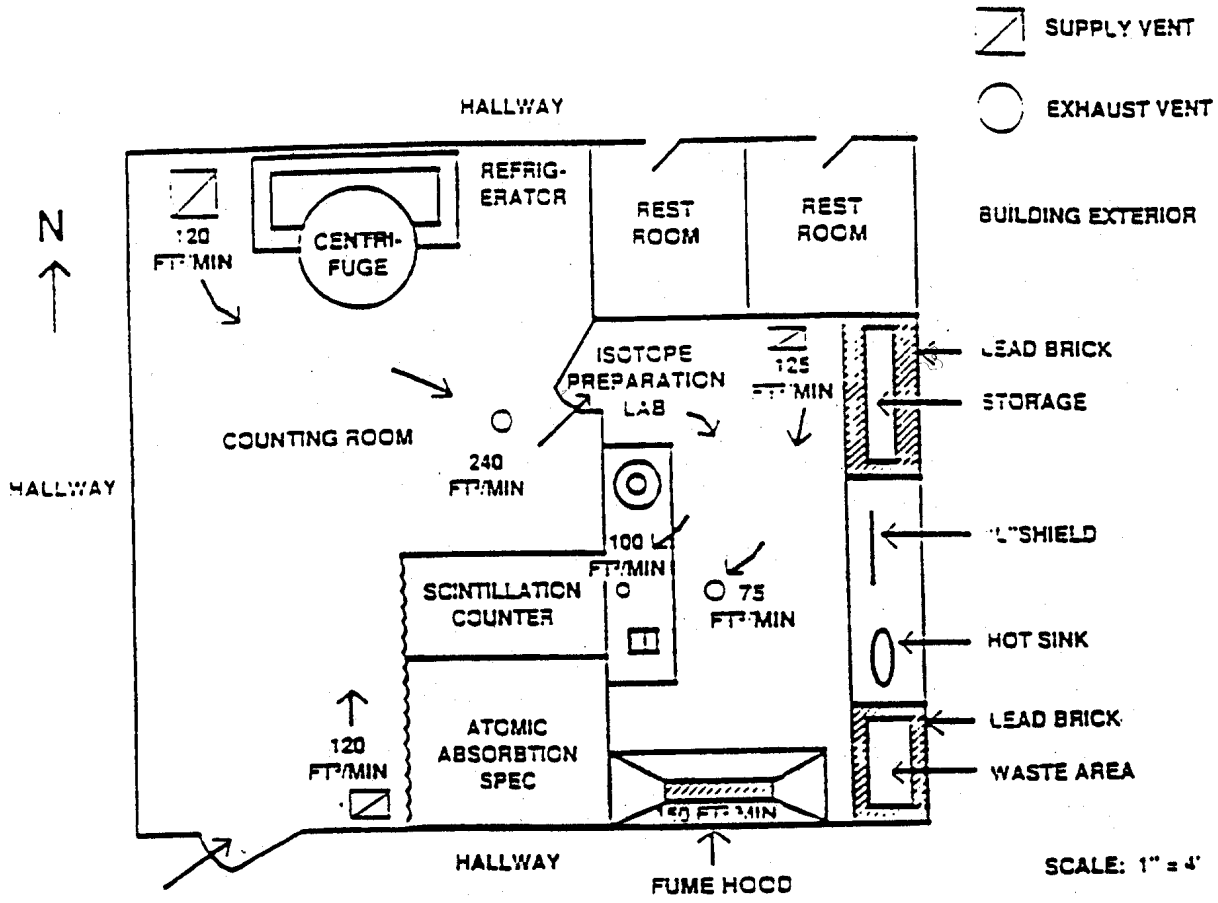
Document	Retention Interval
Radiation Surveys	5 years or until disposal is authorized by the Agency if a survey was used to determine an individual's exposure

II. TEMPORARY JOB SITES

Document	Retention Interval
License and Active Amendments	Until termination of job
Operating/Emergency Procedures	Until termination of job
Latest Leak Test Result	Until termination of job

APPENDIX F

SAMPLE FACILITY DIAGRAM



EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR A FACILITY DESCRIPTION INCLUDING VENTILATION FLOW RATES

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APPENDIX C

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

Among the specific duties and responsibilities of the RSO are the following:

1. Assure that radioactive material possessed by the licensee conforms to the material authorized by the license.

2. Assure that only individuals authorized by the license use the radioactive material.

3. Instruct personnel in proper radiation protection practices.

4. Conduct or have conducted radiation surveys where indicated and keep records of such surveys, including summaries of corrective measures recommended and/or instituted.

5. Assure that personnel monitoring devices are used where indicated, exchanged at required intervals and that records are kept of the results of such monitoring.

6. Assure that interlock switches and warning signals are functioning and that postings are properly located.

7. Investigate each known or suspected case of excessive or abnormal exposure to determine the cause and take steps to prevent its recurrence.

8. Be immediately available to serve as a point of contact with the Agency and give assistance in case of emergency (e.g., damage, fire, theft, etc.);

9. Assure that the Radiation Protection Program is implemented and reviews are performed in accordance with the regulations.

10. Assure that the proper authorities (i.e., the Agency, local police, U.S. Department of Transportation, etc.) are notified promptly in case of accident, damage, theft, or loss of radioactive material; and

11. Assure that the terms and conditions of the license (such as periodic leak tests) are met and that the required records (such as personnel exposure, leak test, accountability, etc.) are maintained and reviewed for compliance with Agency regulations and license conditions.

12. Maintain, for a period of five years, records of all individuals designated by the Radiation Safety Officer to perform duties or meet regulatory requirements that would otherwise be required as a duty of the Radiation Safety Officer. These records shall include:

    A. The name of the designated individual;

    B. A list of all duties the Radiation Safety Officer's designee is authorized to perform;

    C. The date upon which the designation became effective;

    D. The signature of the Radiation Safety Officer's designee; and

    E. The signature of the Radiation Safety Officer.

13. The Radiation Safety Officer shall review records generated by designees and the performance of designees at least once in each calendar quarter. In addition, the licensee shall maintain records, for a period of five years, of these quarterly reviews and Radiation Safety Officer's designee reviews for Agency inspection. These records shall include:

    A. The date of the review;

    B. The records being reviewed or the name of the designee being reviewed;

    C. A list of all duties reviewed by the Radiation Safety Officer for the designee review;

    D. The results of the Radiation Safety Officer's review and any corrective measures taken, if applicable, based on the review; and

    E. The signature of the Radiation Safety Officer.

APPENDIX D

SAMPLE MINIMUM DETECTABLE ACTIVITY CALCULATIONS

Several references contain discussions of counting statistics for radiation measurements. For purposes of this guide, the discussion contained in NCRP Report No. 58 appears to be the simplest to use. The formula we recommend is the one for determining a measurement at the 95% confidence level. The formula for this level is:

$$LLD = \frac{2.71 + 4.65\sqrt{B}}{EFF}$$

where:
LLD = Lower Limit of Detection (dpm, divide by 2.2 E+6 for µCi)
B = Background counting rate (counts/time), and
EFF = Counting efficiency.

The sample counting time and background counting time must be equal. The counting efficiency must be determined by using a standard source of known activity that emits photons of approximately the same energy as the contaminant to be detected. The counting rate for the standard is divided by the standard activity to determine the counting efficiency. When dividing, the two values must be in compatible units. For example, a standard activity in µCi must be converted to dpm by multiplying by a factor of 2.2E+6.

For a copy of the full discussion of the theory and limitations of this test, refer to pages 307-311 in NCRP Report No. 58, A Handbook of Radioactivity Measurement Procedures, issued February 1, 1985 by the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Bethesda, MD 20814.

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APPENDIX E

METHOD FOR CALIBRATING RADIATION SURVEY INSTRUMENTS

1. Application For a Licensee to Perform Radiation Survey Instrument Calibrations

When radioactive material is used to calibrate radiation survey instruments, the person or organization performing the calibration must be specifically authorized by the Agency, the U. S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

An application for a licensee to perform radiation survey instrument calibrations should contain the following information:

a. The manufacturer's name and model of the source(s) to be used.

b. The radionuclide and activity of the radioactive material contained in the source(s).

c. The accuracy of the source(s) activity; documentation that the determination of each source activity is traceable to the National Institute of Standards and Technology - NIST (previously National Bureau of Standards - NBS).

d. A description of the facilities to be used.

e. The name and applicable experience of each individual who will perform the calibrations.

f. Calculations related to the calibration procedures.

g. The step-by-step calibration procedures, including associated radiation safety procedures.

h. Copies of records that will be maintained (see Item 4).

i. Verification that the requirements outlined in this appendix will be followed.

2. Recommended Methods For Calibration of Radiation Survey Instruments

The calibration of radiation survey instruments shall be performed in accordance with the following:

a. The radionuclide sources used for calibration shall approximate point sources.

b. The source activities shall be traceable* within ±5% accuracy to the NIST (previously NBS) calibrations.**

c. The frequency of calibration shall be at intervals not to exceed one year and after servicing/repair.

d. Each scale of the radiation survey instrument shall be calibrated at least at two points such that: (a) one point is in each half of the scale; and (b) the two points are separated by 50-60% of full scale. Logarithmic and digital readout radiation survey instruments with only a single readout scale shall be calibrated, at a minimum, at one point near the midpoint of each decade.

e. The exposure rate measured by the radiation survey instrument should not deviate more than ±10% from the calculated or known value for each point checked. (Read appropriate section of the radiation survey instrument manual to determine how to make necessary adjustments to bring the radiation survey instrument into calibration.) Readings within ±20% will be considered acceptable if a calibration chart or graph is prepared and attached to the radiation survey instrument. If the radiation survey instrument cannot be adjusted so that each reading falls within the ±20% range, it shall be taken out of service and sent to the manufacturer or to a qualified radiation survey instrument laboratory for repair.

f. If an electronic device is used to calibrate instruments, the instrument must still be checked for response to a known source of radiation.

NOTE: Sources of cobalt-60, cesium-137, or radium-226 are appropriate for use in calibrations. The radioactivity of the calibration standard should be sufficient to calibrate the radiation survey instruments on all ranges, or at least up to 1 Roentgen per hour on the higher range radiation measurement instruments. If there are higher ranges, they should be checked for operation and approximately correct response to radiation.

---

* For purposes of this document, the amount of radioactivity in a source is said to be traceable to a national standard when its radioactivity was determined by comparison with a source of the same radionuclide (or a proper simulated source, isotopically) the activity of which is certified by the NIST.

** In lieu of using a traceable radioactive source, a transfer instrument traceable to the NIST, within ±5%, may be used as an alternative standard. For purposes of this document, a transfer instrument shall meet the definition as contained in the American National Standard Institute publication, ANSI N323-1978, "Radiation Protection Instrumentation Test and Calibration."

3. Use of a Reference Check Source for Operational Checks

A reference check source of a long half-life (e.g., greater than five years) shall be used to obtain a radiation survey instrument response by the licensee. The reading shall be taken with the check source placed in a specific geometry relative to the detector, and:

a. Shall be taken before use on each day the instrument is used;

b. Shall be taken after calibration by the licensee or after return to the licensee of a radiation survey instrument sent for calibration by a specifically licensed firm authorized to perform radiation survey instrument calibrations as a customer service;

c. Shall be taken after maintenance and/or each battery change; and

d. Shall be taken at least quarterly.

If any operational check reading using the reference check source, with the same geometry, is not within ±20% of the reading measured immediately after calibration (or upon receipt from a calibration firm), the radiation survey instrument shall be removed from service and recalibrated.

4. Records

Records for Items 2, 3.b, 3.c, and 3.d of this procedure shall be maintained.

a. Records for Item 2 shall include, at a minimum:

1) Radionuclide used;
2) Activity and assay date of source;
3) Present activity;
4) Calculated and measured radiation values, including the percentage of difference;
5) Respective distance from source for each calculated and measured radiation value;
6) Necessary scale correction factors (required if calculated and measured radiation values do not agree within ±10%);
7) Make, model and serial number of radiation survey instrument being calibrated;
8) Name of individual performing the calibration; and
9) Date radiation survey instrument calibration was performed.

b. Records for Items 3.b, 3.c, and 3.d of this procedure shall include, at a minimum:

1) Radionuclide used;
2) Activity and assay date of the radionuclide used;
3) Reading of check source at time of calibration;
4) Geometry of check source relative to detector (position);
5) Date of calibration;
6) Make, model and serial number of the radiation survey instrument;
7) Date reference check was performed; and
8) Name of individual who performed the reference check.

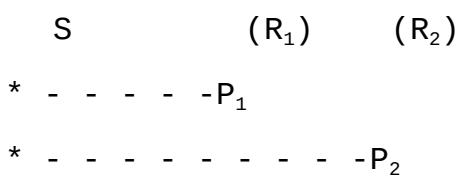
5. Use of Inverse Square Law and Radioactive Decay Law

a. A calibrated source will have a calibration certificate giving its output at a given distance measured on a specific date by the manufacturer or National Institute of Standards and Technology (NIST).

1) The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.

2) The Radioactive Decay Law may be used to calculate the output at other times after the specified date.

b. INVERSE SQUARE LAW:



Exposure rate at P_2:

$$R_2 = \frac{(P_1)^2 \times (R_1)}{(P_2)^2}$$

where:

S is the point source

R_1 and R_2 are the exposure rates at P_1 and P_2 in the same units (mR/hr or R/hr).

P_1 and P_2 are the distances from the point source in the same units
(centimeters, meters, feet, etc.)

c. RADIOACTIVE DECAY LAW:

$R_t = R_o\ e^{-(0.693\ t\ /T_{1/2})}$

where:

R_o and R_t are in the same units (mR/hr or R/hr)

R_o is exposure rate on specified calibration date (time zero)

R_t is exposure rate "t" units of time later

$T_{1/2}$ and t are in the same units (years, months, days, etc.)

$T_{1/2}$ is half-life of the radionuclide

t is the time elapsed between the source calibration (assay) date and the radiation survey instrument calibration date (present time)

d. Example: Source output is given by calibration certificate as 100 mR/hr at 1 foot on March 10, 1985. Radionuclide half-life is 5.27 years.

Question: What is the output at 3 feet on March 10, 1987 (2.0 years later)?

1) Output at 1 foot, 2.0 years after calibration date:

$R_{(1\ ft)} = 100\ mR/hr\ [exp^{-((0.693 \times 2.0)/5.27)}]$

$= 100\ mR/hr\ (0.77)$

$= 77\ mR/hr$ at 1 foot on March 10, 1987

2) Output at 3 feet, 2.0 years after calibration date:

$$R_{(3\ feet)} = \frac{(1\ foot)^2}{(3\ feet)^2}\ (77\ mR/hr)$$

$= 1/9\ (77\ mR/hr)$

$= 8.6\ mR/hr$ at 3 feet on March 10, 1987

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Appendix 1-B

GUIDE TO SI UNITS

RADIATION DOSE EQUIVALENT

OLD (rem)	NEW (sievert)
0.1 mrem	1 µSv
0.25	2.5 µSv
0.5	5 µSv
0.75	7.5 µSv
1 mrem	10 µSv
2.5	25
10 mrem	100 µSv (0.1 mSv)
100 mrem	1 mSv
500 mrem	5 mSv
1 rem	10 mSv
1.5 rem	15 mSv
5	50
10 rem	100 mSv
15 rem	150 mSv
50 rem	500 mSv
100 rem	1 Sv

1 Sv = 100 rem
1 Gy = 100 rad
(gray)

RADIATION DOSE RATES:

µSv/h, mSv/h
e.g., 7.5 µSv/h
25 µSv/h

AMOUNT OF RADIOACTIVE MATERIAL

OLD Ci (curie)	NEW Bq (bequerel)
1 pCi	37 mBq
27 pCi	1 Bq
1 nCi	37 Bq
27 nCi	1 kBq
1 µCi	37 kBq
27 µCi	1 GBq
1 mCi	37 MBq
27 mCi	1 GBq
1 Ci	37 GBq
27 Ci	1 TBq

1 ton = 1 Mg = 1000 kg
1 kg = 1000 g
1 MBq/ton = 1 Bq/g

Derived Air Concentration (DAC)
Units: Bq m^{-3}

Conversion
µCi cm^{-3} x 3.7 $x10^{10}$ = Bq m^{-3}

$$\frac{\text{dpm } m^{-3}}{60} = \text{Bq } m^{-3}$$

SURFACE ACTIVITY LEVELS

µCi/cm²	Bq/cm²	(kBq/m²)
10^{-6}	0.037	0.37
3 x 10^{-6}	0.1	1.0
10^{-5}	0.37	3.7
3 x 10^{-5}	1	10
10^{-4}	3.7	37
3 x 10^{-4}	10	100
10^{-3}	37	370
3 x 10^{-3}	100	1000
10^{-2}	370	3700

(1 m^2 = 10^4 cm^2)

CONCENTRATION IN SOLUTION

µCi/l	(kBq/m²) (kBq/l)
1	37
10	370
100	3700

1 m^3 = 10^3 dm^3 = 10^3 l or 10^3 L
1 MBq/m^3 = 1 kBq/dm^3

SI UNITS PREFIXES:

a	atto	10^{-18}		k	kilo	10^3	thousand
f	femto	10^{-15}		M	mega	10^6	million
p	pico	10^{-12}	million millionth	G	giga	10^9	thousand million
n	nano	10^{-9}	thousand millionth	T	tera	10^{12}	million million
µ	micro	10^{-6}	millionth	P	peta	10^{15}	
m	milli	10^{-3}	thousandth	E	exa	10^{18}	

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APPENDIX G
BASIC SUBJECTS TO BE COVERED DURING RADIATION SAFETY TRAINING

I. Fundamentals of Radiation Safety

- A. Characteristics of radiation
- B. Units of radiation dose and quantity of radioactivity
- C. Math and calculations basic to the use and measurement of radioactivity.
- D. Significance of radiation dose
  1. Radiation protection standards
  2. The ALARA principle
  3. Biological effects of radiation
- E. Levels of radiation from sources of radiation
- F. Methods of controlling radiation dose
  1. Working time
  2. Working distance
  3. Shielding

II. Radiation Detection Instrumentation to be Used

- A. Use of radiation survey instruments
  1. Operation
  2. Calibration
  3. Limitations
- B. Survey techniques
- C. Use of personnel monitoring equipment
  1. Film badges
  2. Thermoluminescent dosimeters (TLD's)
  3. Pocket dosimeters

III. Safety Equipment to be Used

- A. Remote handling equipment
- B. Fume Hoods
- C. Storage containers
- D. Personnel protective equipment (i.e., gloves, lab coats, respirators)

IV. The Requirements of Pertinent Federal and State Regulations (see Section I.D. of guide)

V. Terms and Conditions of the License, Active Amendments, and Any Correspondence Submitted in Support of the License Application

VI. The Licensee's Written Operating and Emergency Procedures

VII. Manufacturer's Instruction Manuals for Sources/Devices

VIII. On-the-job Training

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APPENDIX H

SAMPLE PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The Radiation Safety Officer (RSO) must approve or place all orders for radioactive material and must ensure that the requested material and quantities are authorized by the license and that possession limits are not exceeded.

2. During normal working hours, carriers must be instructed to deliver radioactive packages directly to the Radiation Safety Department.

3. During off-duty hours, security personnel must accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below.

SAMPLE MEMORANDUM

MEMORANDUM FOR: Security Personnel

FROM: John Jones,
Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

If the package is wet or appears to be damaged, immediately contact the facility's RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.

Any packages containing radioactive material that arrive between 4:30 P.M. and 7:00 A.M. or on Sundays shall be signed for by the Security guard on duty and taken immediately to the Radiation Safety Department. Unlock the door, place the package on top of the counter immediately to the right of the door, and relock the door.

RADIATION SAFETY OFFICER (RSO): _____

OFFICE PHONE: _____

HOME PHONE: _____

RADIATION CONTROL PROGRAM, MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH 24-HOUR PHONE: (617) 727-9710

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APPENDIX I

PROCEDURE FOR SAFELY OPENING
RADIOACTIVE MATERIAL PACKAGES

For packages received under the specific license, authorized individuals shall implement procedures for opening each package as follows:

1. a. Put on gloves to prevent hand contamination;

   b. Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form radioactive material as defined in 105 CMR 120.005;

      AGENCY NOTE: Labeled means labeled with a Radioactive White I, Yellow II or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440, published October 1, 1993, exclusive of subsequent amendments or editions.

   c. Visually inspect the package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop and notify the Radiation Safety Officer (RSO).

   d. Monitor the external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 105 CMR 120.772, as listed in 49 CFR 173.435 published October 1, 1993, or as derived from 49 CFR 173.433 published October 1, 1993; and

   e. Monitor all packages known to contain radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

2. The monitoring required by Item 1 above shall be performed as soon as practicable after receipt of the package, but not later than three (3) hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours or if there is evidence of degradation of package integrity, such as a package that is crushed, wet or damaged. If a package is received after working hours, and has no evidence of degradation of package integrity, the package shall be

monitored no later than three (3) hours from the beginning of the next working day.

3. Open the outer package (following supplier's directions if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip, and label on bottle or syringe holder). Check integrity of the final source container (inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material). Check also that the shipment does not exceed license possession limits. If anything is other than expected, stop and notify the RSO.

4. Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate all radiation labels prior to discarding in regular trash.

5. Maintain records of receipt, package survey and wipe test results.

6. The final carrier and the Agency shall be immediately notified by telephone and shall confirm the initial contact within 24 hours by overnight letter or telefacsimile to the Agency, when:

   a. Removable radioactive surface contamination exceeds the limits of 105 CMR 120.785(H); or

   b. External radiation levels exceed the limits of 105 CMR 120.785(I) and(J).

APPENDIX J

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive material is used.

2. Wear disposable gloves at all times while handling radioactive material.

3. Monitor hands, shoes, clothing, and work surfaces with a low-level G-M survey instrument (if appropriate, for radionuclides in use) for contamination after each use of radioactive material or before leaving the restricted area.

4. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

5. Do not store food, drink, or personal items in any area where radioactive material is stored or used.

6. Secure all areas where radionuclides are used/stored when unattended.

7. Wear whole-body personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive material is used or stored if required by the regulations or the terms of your license. These must be worn at chest or waist level where the highest exposure is expected (outside of any lead aprons).

8. When required to wear film or TLD finger badges, they must be turned inward towards material.

9. Dispose of radioactive waste only in specially designated/labelled receptacles.

10. Store and label radioactive materials correctly.

11. Use alarms and interlocks, and post areas as required.

12. Never pipette by mouth.

13. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level if applicable.

14. Always transport radioactive material in shielded containers with sufficient absorbent material.

15. Use absorbent material on countertops where radioactive material is used.

16. Use suitable ventilation systems when handling gases or volatile material.

APPENDIX K

EMERGENCY PROCEDURE

1. **MINOR SPILLS:**

   a. NOTIFY: Notify persons in the area that a spill has occurred.

   b. PREVENT THE SPREAD: Cover the spill with absorbent material, and prevent access to the area by unauthorized personnel.

   c. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent material. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

   d. SURVEY: With a low range, thin window G-M survey instrument, check the area around the spill, hands, and clothing for contamination. For alpha and low-energy beta emitters, conduct wipe tests at the spill area.

   e. REPORT: Report incident to the Radiation Safety Officer (RSO).

2. **MAJOR SPILLS:**

   a. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

   b. PREVENT THE SPREAD: Cover the spill with absorbent material, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

   c. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing radiation exposure.

   d. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

   e. CALL FOR HELP: Notify the RSO immediately.

   f. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the RSO. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water. Injured persons should be decontaminated and first aid performed as necessary. If life threatening injuries are present, the individual should be given immediate

life-saving first aid and transported to a hospital for further medical treatment regardless of any contamination present. The hospital should be given prior notification that the patient is contaminated so that the appropriate controls can be implemented.

3. **EXPOSURE TO SOURCES OF RADIATION**

Terminate the source of exposure and prevent others from being exposed. Use additional shielding as needed. Notify the Radiation Safety Officer so the nature and extent of exposure can be determined. Seek medical attention if severe exposure is suspected.

4. **LOSS, THEFT, OR DAMAGE TO A SOURCE OF RADIOACTIVE MATERIAL**

In addition to following the applicable procedures outlined above, notify the RSO immediately and the Agency at (617) 727-6214.

RADIATION SAFETY OFFICER (RSO):_____

OFFICE PHONE:_____ HOME PHONE:_____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RSO:

_____

APPENDIX L

AREA SURVEY PROCEDURE

1. All preparation and use areas will be surveyed each day of use with a low-range survey instrument (as appropriate for radionuclides used) and decontaminated if necessary.

2. Individuals shall monitor hands, shoes, clothing, and work surfaces with a low-range survey instrument (as appropriate for radionuclides used) for contamination after each use of radioactive material or before leaving the restricted area and decontaminate as necessary.

3. Laboratory areas where only small quantities of radioactive material are used [less than 7.4 MBq (200 µCi)] or areas where material is in storage only will be surveyed monthly.

4. Waste storage areas and all other laboratory areas [those using greater than or equal to 7.4 MBq (200 µCi)] will be surveyed weekly.

5. The weekly and monthly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 1.0 uSv (0.1 mrem) per hour for the radionuclide involved.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect [3.7 Bq (220 dpm) per 100 cm^2, beta/gamma], for the contaminant involved. Wipes for areas of use or other high-background areas will be removed to a low-background area for measurement.

6. If contamination is detected, the area will:

   a. Be cleaned or posted and restricted from use if the contamination level exceeds [37 Bq (2,200 dpm) per 100 cm^2, beta/gamma]; or

   b. Be covered, cleaned, or identified to all employees if the contamination level exceeds [3.7 Bq (220 dpm) per 100 cm^2] but is less than [37 Bq (2,200 dpm) per 100 cm^2, beta/gamma].

7. Records of all area survey results, including negative results, will be kept for [five (5) years] after each survey. The record will include:

   a. Manufacturer, model, and serial number of the instruments used to perform surveys and analyze wipe tests.

   b. Date of the survey.

   c. A drawing of the area surveyed identifying relevant features such as active storage areas, active waste areas, etc.

   d. Measured dose rates (in units of sieverts or mrem per hour) keyed to locations on the drawing.

   e. Detected contamination levels [in units of Bq/100 cm^2, dpm/100 cm^2 or microcuries/100 cm^2] keyed to locations on the drawing.

   f. Corrective action taken in the case of contamination or exposure rates in excess of action levels or the regulations, reduced contamination levels or dose rates after corrective action, and any appropriate comments.

   g. The identification of the individual performing the survey.

NOTE: For the surveys referenced in Items 1. and 2. above, only the date and the identification of the person performing the survey need to be recorded when no abnormal radiation levels are identified. If abnormal radiation levels or personnel contamination are noted, survey results should be documented as per Item 7 above.

APPENDIX M

TESTING SEALED SOURCES FOR LEAKAGE AND/OR CONTAMINATION

Applicants who wish to perform their own tests for leakage and/or contamination, including the procurement and the analysis of the test samples, must submit the following descriptive information in support of the application:

1. Describe all instrumentation which will be used for the analysis of the test samples. The descriptive information should include:

   a. The manufacturer, model, [and serial number] of each instrument;

   b. The types and energies of detectable radiation, as applicable to each instrument;

   c. The efficiency of each instrument, for each type of radioactive material to be tested, including the supportive calculations documenting such efficiency; and

   d. The minimum sensitivity of each instrument, for each type of radioactive material to be tested, including the supportive calculations documenting such minimum sensitivity. At a minimum, the instrument used must be capable of detecting 185 Bq (0.005 µCi) of the radioactive material being tested. For radium-226, the instrument must be sensitive enough to detect 185 Bq (0.005 µCi) external radon-daughter contamination or the escape of radon at the rate of 37 Bq (0.001 µCi) per 24 hours.

2. Identify the calibration standards to be used in the analysis of each radioactive material to be tested. The identification shall include the manufacturer, model, radionuclide and activity of each standard. Such standards shall be traceable to a national standard.

3. Describe the calibration procedures and the frequency of calibration for each instrument.

4. Describe the material or leak test kit to be used in collecting the leak test samples.

5. Describe in detail the procedure for performing the analysis of the leak test samples.

6. Submit sample calculations showing the conversion of the raw counting data to units of becquerels or microcuries.

7. Describe the method for disposing of contaminated leak test samples.

8. Describe the training and experience of each person who will analyze and evaluate the results of the leak test samples.

9. Describe the records to be maintained for each leak test. These shall include:

   a. The location of the source which was leak tested;

   b. The date the sample was collected;

   c. The individual collecting the sample;

   d. The person performing the analysis;

   e. The date the analysis was performed;

   f. The unique identification of the source tested; e.g., manufacture, model number, serial number, etc.

   g. The radionuclide and the activity of radioactive material contained in the source; and

   h. The results of the test expressed in units of becquerels or microcuries. Actual test results shall be reported unless such results are less than 185 Bq (0.005 μCi).

APPENDIX N

RADIOIODINE BIOASSAY PROCEDURE

Calibration

This bioassay procedure uses a sodium iodide crystal and single channel analyzer (such as an uptake probe) to determine thyroid burden. Calibration of the system will be performed annually.

A. Set Window or Region of Interest

The window or region of interest must be set to detect emissions for the radionuclide you are trying to detect. In the case of I-131, the region of interest must be in the area of 364 keV.

Using the minimum detectable activity calculations described in Appendix D, demonstrate that the system you are using can detect 1.48 kBq (0.04 µCi) of I-131. (Submit these calculations with Exhibit B.)

B. Establish Background

Hold probe on thigh (ensure thigh and/or lab coat are not contaminated) for a 1 minute count. Record results.

C. Count Standard

A known (measured) amount of radioactivity must be used as the standard. When assaying for I-131, an I-131 standard (or a standard source of known activity that emits photons of approximately the same energy as I-131, e.g., Ba-133) must be used. I-131 liquid or capsule may be used, and must be measured and corrected for decay. Place the standard in a thyroid phantom*. Hold probe against the phantom in an established geometry, similar to the geometry to be used when performing a bioassay on an individual, for required amount of time (1 min.). Record results.

(*Note: Specifications for design of a neck phantom can be found in American National Standard ANSI N44.3-1973, "Thyroid Radioiodine Uptake Measurements Using a Neck Phantom.")

D. Establish System Efficiency

Standard CPM - Background CPM = Net Standard CPM

$$\frac{\text{Net Standard CPM}}{\text{Standard Activity}(\mu\text{Ci})} \times \frac{100}{2.2 \times 10^6 \text{ DPM}/\mu\text{Ci}} = \% \text{ Efficiency}$$

Investigation Limits

E. Establish In-House Investigation Limits

1. The Radiation Safety Officer (RSO) shall be notified whenever the thyroid burden at the time of measurement exceeds 37 kBq (1.0 µCi) of I-131. The RSO shall perform an investigation into the cause of the exposure and the potential for further exposure, and develop corrective actions to prevent recurrence.

2. The RSO shall be notified immediately whenever the thyroid burden at the time of measurement exceeds 185 kBq (5.0 µCi) of I-131. The RSO must perform an investigation, as described above, and must perform weekly bioassays on the individual until the individual's thyroid burden is less than 37 kBq (1.0 µCi) of I-131.

(Note: In-house investigation limits are adopted from U. S. Nuclear Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program.")

Measurement

F. Measure Thyroid Gland

1. Perform measurements in a low-background area.

2. Hold probe on thigh (ensure thigh and/or lab coat are not contaminated) for a 1 minute count. Record results.

3. Hold probe in the center of neck near Adam's apple for required amount of time (1 min). Record results.

4. Subtract background from thyroid gland count to obtain net counts. Record results.

5. Calculate and record the amount of radioactivity in thyroid by using the equation below:

A. $$\frac{\text{Net counts (CPM)} \times 100}{\%\ \text{Efficiency} \times 2.2 \times 10^6\ \text{dpm/µCi}} = \frac{X}{}\ \text{µCi}$$

B. The intake retention fraction (t = 24 hours) for I-131 is 0.133.

$$\frac{X\ \text{µCi}}{0.133} = \frac{X(i)}{}\ \text{µCi (estimate of intake)}$$

C. The inhalation ALI for I-131 is 50 µCi

$$\frac{X(i)}{50\ \mu Ci} = \%\ \text{of CEDE}$$

6. If results are less than the investigation limits established in E.1. above, you are finished.

7. If results are more than the investigation limits established in E. above, notify the RSO immediately. The RSO may restrict the employee's further handling of I-131 until the thyroid burden is measured to be below the reporting limits established in E above.

NOTE: For other radioisotopes of iodine, corrections for effective half-life, inhalation ALI, instrument efficiency, intake retention factors and action levels must be made.

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APPENDIX O

SAMPLE CALCULATIONS FOR RADIOACTIVE GASES/VOLATILE MATERIAL

The following information must be submitted in support of requests to use radioactive gases:

1. CALCULATIONS OF MINIMUM VENTILATION RATES FOR RESTRICTED AREAS REQUIRED BY PART 340

   a. Determine the highest dose to an individual from all external radiation for the previous 12-month period by reviewing personnel monitoring records (film, TLD, etc.) or based on activity, distance and duration of handling. If necessary, modify the dose to account for an anticipated increase or decrease in potential exposure.

   b. Modify the DAC value to allow for the estimated annual external exposure.

      A simplified method is to subtract the estimated external dose from the occupational dose limit of 50 mSv (5 rems) and divide this number by 50 mSv (5 rems). This yields the fraction of the dose limit of 5 rems that would still be permitted from internal sources. Multiplying this fraction times the DAC value yields a modified DAC. These DAC values are provided in Appendix B to 10 CFR § 20.1001-20.2401 in Table 1, Column 3.

   Example:

   A new room is being designed where Kr-85 will be used. If the annual external dose is 2 rems, the modified DAC value should be based on 3 rems that could still be incurred from internal exposure. The listed DAC value for Kr-85 is 1E-4 µCi/ml.

$$DAC(modified) = \frac{3rems}{5rems} \; x \; 1E\text{-}4 \; \mu Ci/ml$$

$$= 6E\text{-}5 \; \mu Ci/ml$$

   If the facility in question plans to use 5.2 x 10^6 µCi of Kr-85 per year. What ventilation rate is required to ensure compliance with 105 CMR 120.211?

   Maximum Activity:

   A_0 = 5.2 x 10^6 µCi/year

   Assume a loss rate (f) of 20%

$A = A_0 \times f$

$A = (5.2 \times 10^6\ \mu Ci/year) \times 0.2$

$A = 1 \times 10^6\ \mu Ci/year$

Required Ventilation Rate:

$V = \frac{A}{C}$ where $C = DAC = 6 \times 10^{-5}\ \mu Ci/ml$

$$V = \frac{1 \times 10^6\ \mu Ci/year}{6 \times 10^{-5}\ \mu Ci/ml}$$

$V = 1.7 \times 10^{10}$

$$V = \frac{1.7 \times 10^{10}\ ml}{year} \times \frac{1\ year}{52\ weeks} \times \frac{1\ week}{40\ hours} \times \frac{1\ hour}{60\ minutes} \times \frac{1\ ft^3}{2.832 \times 10^4\ ml}$$

$V = 4.8\ ft^3/min$

The answer shows that, in order to meet the requirements of 105 CMR 120.534, the laboratory (RESTRICTED AREA) must have a ventilation rate of at least 5.0 ft^3/min with no recirculation of air. Where practicable, the ventilation rate should be greater than that shown necessary by the calculations. Consider every alternative in order to maintain the air concentration of Kr-85 as low as is reasonably achievable.

If the ventilation rate is inadequate to meet the requirements of 105 CMR 120.534, methods of increasing ventilation or reducing the activity must be implemented.

2. AIR CONCENTRATIONS OF RADIOACTIVE GASES/VOLATILE MATERIAL IN UNRESTRICTED AREAS

Licensees who make releases of radioactive gases/volatile material to unrestricted areas during use, storage, and disposal are required to perform surveys (measurements or calculations) to ensure that they are in compliance with 105 CMR 120.534. Many facilities do not have sufficient air flow to achieve the necessary dilution to unrestricted areas. The following procedure may be used to estimate the concentrations of radioactive gases in effluents to unrestricted areas:

a. Estimate the maximum amount of radioactive gas/volatile material to be released per year (A). This should include all anticipated losses during use, storage and disposal.

b. Determine the flow rate of the exhaust system, and calculate the air flow per year (V).

c. For unrestricted areas, 105 CMR 120.222 requires that the air concentration (C):

$$C = \frac{A}{V} \leq \text{Maximum concentration as listed in Table II, Column I of 10 CFR 20 Appendix A.}$$

d. Sample Problem:

A laboratory plans to use 5×10^6 µCi of Kr-85 per year. A fume hood is available for the release of Kr-85, and has a measured airflow of 168 ft/min. with an opening of 8 ft^2. What is the average concentration of Kr-85 at the point of release from the fume hood exhaust (assuming all Kr-85 from collection bags, filters, etc. has been released)?

Volume:

($1\ ft^3/min = 1.7 \times 10^6$ ml/hr = 6.8×10^7 ml/40-hr wk = 1.5×10^{10} ml/yr)

$$V = 168\ \frac{ft}{min} \times 8\ ft^2 \times 1.5 \times 10^{10}\ \frac{ml/yr}{ft^3/min}$$

$$V = 1344\ \frac{ft^3}{min} \times 1.5 \times 10^{10}\ \frac{ml/yr}{ft^3/min}$$

$$V = 2.02 \times 10^{13}\ ml/yr$$

Concentration:

$$C = \frac{5.2 \times 10^6\ \mu Ci/year}{2.02 \times 10^{13}\ ml/yr}$$

$$C = 2.6 \times 10^{-7}\ \mu Ci/ml$$

The concentration of radioactive gas vented to the atmosphere is less than the maximum concentration of 7×10^{-7} µCi/ml listed in Table II, Column I of 10 CFR 20 Appendix A.

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APPENDIX P

DIRECT READING DOSIMETER USE AND CALIBRATION

USE OF DIRECT READING DOSIMETERS

1. Each direct reading dosimeter (dosimeter) used must have been calibrated within one year prior to its use.

2. Only one person shall be assigned to a dosimeter at any one time.

3. A log must be made to document the measured exposures of each individual using a dosimeter. This log shall record the date and time of each entry and the name and social security number of the monitored individual.

4. At the beginning of each shift, or prior to entering an area where dosimeters are needed, the dosimeter must be zeroed (charged) to indicate essentially no exposure. If this is not practicable, document the initial exposure reading in the dosimeter log.

5. Enter the exposure reading from the dosimeter in the dosimeter log daily (immediately before the end of a shift, or after all entries into a restricted area have been performed).

6. The Radiation Safety Officer must be notified immediately if a dosimeter is discharged beyond its range.

7. At least once each month, total the exposures in the log for each individual who used a dosimeter during that period. These totals may be kept in the log or with other dosimetry results maintained by the licensee.

CALIBRATION OF DIRECT READING DOSIMETERS

1. The calibration of a direct reading dosimeter (dosimeter) shall be performed in accordance with the following:

   a. The radionuclide sources used for calibration shall be approximate point sources.

   b. The source activities shall be traceable within 5% accuracy to NIST.

   c. The dosimeter shall be calibrated at two scale readings, separated by at least 50 percent of the full-scale reading.

d. The exposure measured by the dosimeter shall not differ from the calculated (true) exposure by more than ± 20 percent of the calculated (true) value.

e. Dosimeters shall be charged, placed in a radiation-free environment (excluding background radiation), then read after a minimum of 24 hours has passed. A dosimeter shall be considered defective if the rate of leakage is greater than 5 percent of the dosimeter full-scale reading.

2. Records of calibration shall include:

a. Radionuclide used,

b. Activity and activity assay date of source,

c. Date of dosimeter calibration,

d. Activity of source at date of dosimeter calibration,

e. Calculated (true) and measured radiation values,

f. Respective distance from source for each calculated and measured radiation value,

g. Elapsed time of exposure for each measured radiation value,

h. Necessary scale correction factors (required if calculated and measured radiation values do not agree within ± 20 percent),

i. Make, model, and serial number of dosimeter calibrated, and

j. Signature of individual who performed the calibration.

EXHIBIT A

APPLICATION FORM FOR (NON-MEDICAL) RADIOACTIVE MATERIALS LICENSE

(MRCP 120.100-4)

RADIOACTIVE MATERIALS LICENSE APPLICATION
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH, RADIATION CONTROL PROGRAM

INSTRUCTIONS - Complete all items in this application for a new license or the renewal of an existing license. Use supplemental sheets where necessary. Item 13 must be completed on all applications. Mail the completed application to: The Radiation Control Program, 174 Portland Street, 5th Fl. Boston, MA 02114. Upon approval of this application, the applicant will receive a State of Massachusetts Radioactive Material License.

1. THIS IS AN APPLICATION FOR ☐ A. NEW LICENSE ☐ B. AMENDMENT TO LIC.NO._____ ☐ C. RENEWAL OF LICENSE NO._____	2. NAME AND MAILING ADDRESS OF APPLICANT(Include zip code)
3. ADDRESSES WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.	
4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION.	TELEPHONE NUMBER
SUBMIT ITEMS 5 THROUGH 12 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.	
5. RADIOACTIVE MATERIAL a. Element & mass number; b. Chemical and/or physical form; c. Maximum amount that will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFTY PROGRAM AND THEIR TRAINING AND EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT (INCLUDE MINIMIZATION STATEMENT/PLAN).	12. CORPORATE STRUCTURE

ITEM 13 - CERTIFICATE
(This item must be completed)

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH APPLICABLE STATE REGULATIONS AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

_____ By: _____
TYPE OR PRINT NAME OF CERTIFYING OFFICIAL SIGNATURE

_____ Date: _____
TITLE OF CERTIFYING INDIVIDUAL

EXHIBIT B

INSTRUMENTATION FORM

1. Portable Radiation Detection Survey Instruments
(0.1 mrem/hr to 50 mrem/hr or 1 uSv/hr to 500 uSv/hr):

Manufacturer: _____

Model: _____

Available: _____

Range: _____

Window Thickness: _____
(mg/cm^2)

Detector Type: _____
(G-M, Ion Chamber, etc.)

2. Portable Radiation Measurement Survey Instruments
(1 mrem/hr to 1000 mrem/hr or 10 µSv/hr to 10 mSv/hr):

Manufacturer: _____

Model: _____

Available: _____

Range: _____

Window Thickness: _____
(mg/cm^2)

Detector Type: _____
(G-M, Ion Chamber, etc.)

3. Fixed Area Monitor

Manufacturer: _____

Model: _____

Available: _____

Range: _____

4. Liquid Scintillation Counter (If used to analyze wipes*)

Manufacturer: _____

Model: _____

Minimum Detectable Activity*: _____

5. Well Counter (If used to analyze wipes*)

Manufacturer _____

Model: _____

Minimum Detectable Activity*: _____

6. Instrument Used for Analysis of Wipe Tests*

(Generic Description) _____

Manufacturer: _____

Model: _____

Minimum Detectable Activity*: _____

7. Thyroid Bioassay Probe

Manufacturer: _____

Model: _____

Range/Minimum Detectable Activity*: _____

8. Other Instruments (Continue on separate sheet if necessary.)

(Generic Description) _____

Manufacturer: _____

Model: _____

Range: _____

* Submit calculations as described in Appendix D.

Massachusetts Department of Public Health
Radiation Control Program
174 Portland Street, 5th Floor
Boston, MA 02114

The Agency is requesting disclosure of information that is necessary to accomplish the statutory purpose as outlined under M.G.L. c. 111, §§ 3, 5M, 5N, 5O, 5P. Disclosure of this information is required. Failure to provide any information will result in this form not being processed.

CERTIFICATE - TERMINATION
DISPOSITION OF RADIOACTIVE MATERIAL

LICENSEE NAME: S))))))))))))))))Q **LICENSE NUMBER:** S))))))Q

ADDRESS: S))))))))))))))))Q

S))))))))))))))))Q

The following information is provided in accordance with 105 CMR 120.132, "Expiration and Termination of Licenses." This regulation is attached to this form. Complete the items below which are applicable to your licensed activity:

__ **1. All use of radioactive materials authorized under the above referenced license has been terminated.**

__ **2. Radioactive contamination has been removed to the level outlined in 105 CMR 120. 291 to the extent practicable.**

__ **3. All radioactive material previously procured and/or possessed under the authorization granted by the above referenced license has been disposed of as follows:**

__ **Transferred to (Name and Address):** _____

_____

_____

which is authorized to possess such material under License Number _____

issued by (Licensing Agency): _____

__ **Decayed, surveyed and disposed of as non-radioactive trash.**

__ **Licensed under License Number:** _____

issued by (Licensing Agency): _____

__ **No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license.**

__ **Other (Attach additional pages).**

__ **4. Attached are radiation surveys or the equivalent as specified in 105 CMR 120.132(I)(2).**

__ **5. Additional remarks. (Attach additional pages).**

THE UNDERSIGNED, ON BEHALF OF THE LICENSEE, HEREBY CERTIFIES THAT LICENSABLE QUANTITIES OF RADIOACTIVE MATERIAL UNDER THE JURISDICTION OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM ARE NOT POSSESSED BY THE LICENSEE. IT IS THEREFORE REQUESTED THAT THE ABOVE REFERENCED LICENSE BE TERMINATED.

DATE: _____ **SIGNATURE:** _____

TITLE: _____